



Phentermine and fenfluramine (“Phen-fen”)<sup>3</sup> were prescribed for Plaintiff by physician’s assistant, Mark Wisner, P.A., (“Dr. Wisner”), for the treatment of obesity.<sup>4</sup> Plaintiff consumed the drugs for approximately two months, in 1996. Plaintiff claims that she was diagnosed with “moderately severe and possibly even severe” aortic regurgitation, in addition to moderate mitral regurgitation, on January 18, 2001. She attributes her alleged injuries to her use of fenfluramine.

Plaintiff’s Petition against Defendants American Home Products Corporation, Wyeth, A-H Robins Company, Inc., Interneuron Pharmaceuticals, Inc., Wal-Mart Stores, Inc., Medicine Shoppe International, Inc., and Walgreen Company<sup>5</sup> enumerates the following six theories of liability: (1) breach of warranty; (2) strict liability-design defect; (3) strict liability-failure to warn; (4) negligence; (5) violation of the Deceptive Trade Practices Act; and (6) fraud.<sup>6</sup> On December 4, 2002, Defendant Wyeth removed the case to this Court pursuant to 28 U.S.C. § 1441, asserting jurisdiction under 28 U.S.C. § 1332.

## **II. SUMMARY JUDGMENT STANDARD**

Pursuant to Federal Rule of Civil Procedure 56(c), a court may grant a motion for

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<sup>3</sup> When fenfluramine was prescribed in combination with the drug phentermine, it was commonly referred to as “phen-fen.”

<sup>4</sup> In his deposition, Dr. Wisner testified that he is a family practice physician’s assistant who operates dependently under the supervision of a supervising physician. Dr. Wisner further testified that he prescribed Plaintiff phen-fen under the supervision of Eduardo Franciso, M.D. (Dr. Franciso). *See* Pl.’s Opp’n to Def.’s Mot. for Summ. J., Ex. C

<sup>5</sup> On November 15, 2006, Plaintiff voluntarily dismissed all claims against Defendants Interneuron Pharmaceuticals, Inc.; Walgreen Company; Wal-Mart Stores, Inc.; and the Medicine Shoppe International, Inc.

<sup>6</sup> Plaintiff voluntarily dismissed her claims against Defendant for fraud and violation of the Deceptive Trade Practices Act. *See* Pl.’s Response to Def.’s Mot. for Summ. J., Ex. G. The Court will deny Defendant’s Motion for Summary Judgment on these claims as moot.

summary judgment only if all of the information before the court shows “there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The United States Supreme Court has noted that “summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the federal rules as a whole, which are designed to ‘secure the just, speedy and inexpensive determination of every action.’” *Id.* at 327 (quoting Fed. R. Civ. P. 1). “By its terms, [Rule 56(c)(1)] provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for judgment; the requirement is that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Material facts are those “that might affect the outcome of the suit under the governing law,” and a genuine material fact is one such that “a reasonable jury could return a verdict for the nonmoving party.” *Id.*

If the non-moving party has failed to “make a showing sufficient to establish the existence of an element essential to that party’s case, . . . there can be ‘no genuine issue as to any material fact,’ since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” *Celotex*, 477 U.S. at 322-23. “Thus, where the moving party can point to the absence of any evidence satisfying a necessary element of a claim, such as damages, and the non-moving party fails to produce any such evidence, summary judgment is properly entered.” *Meterlogic, Inc. v. KLT, Inc.*, 368 F.3d 1017, 1018 (8th Cir. 2004).

The initial burden of proof in a motion for summary judgment is placed on the moving party to establish the non-existence of any genuine issue of fact that is material to a judgment in

its favor. *City of Mt. Pleasant, Iowa v. Associated Elec. Co-op., Inc.*, 838 F.2d 268, 273 (8th Cir. 1988). Once this burden is discharged, if the record does, in fact, bear out that no genuine dispute exists, the burden then shifts to the non-moving party who must set forth affirmative evidence and specific facts showing there is a genuine dispute on that issue. *Anderson*, 477 U.S. at 249. When the burden shifts, the non-moving party may not rest on the allegations in its pleadings, but by affidavit and other evidence must set forth specific facts showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(e); *Stone Motor Co. v. Gen. Motors Corp.*, 293 F.3d 456, 465 (8th Cir. 2002). To meet its burden, the non-moving party must “do more than simply show there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In fact, the non-moving party must show there is sufficient evidence favoring the non-moving party which would enable a jury to return a verdict for it. *Anderson*, 477 U.S. at 249; *Celotex*, 477 U.S. at 324. “If the non-moving party fails to produce such evidence, summary judgment is proper.” *Olson v. Pennzoil Co.*, 943 F.2d 881, 883 (8th Cir. 1991).

## II. DISCUSSION

The parties and the Court agree that Kansas substantive law controls this products liability case. The parties dispute whether Plaintiff’s claims for negligence, breach of warranty and strict liability-design defect should be construed as failure to warn claims. Defendant contends that Plaintiff’s claims are grounded upon failure to warn and, therefore, the Court should apply the learned intermediary doctrine<sup>7</sup> to each cause of action. Plaintiff counters that her claims are not

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<sup>7</sup> Under the learned intermediary doctrine, a prescription drug manufacturer’s duty to warn “is satisfied when the prescribing doctor is informed of a drug’s inherent risks.” *Nichols Central Merch., Inc.*, 16 Kan. App. 2d 65, 67 (Kan. Ct. App. 1991). According to the Kansas Supreme

based solely on Defendant's failure to warn. Plaintiff notes that she asserts claims against Defendant for design defect, based upon the fact that fenfluramine was an unreasonably dangerous drug; negligence in the design, testing and manufacturing of fenfluramine; and breach of express and implied warranties, for selling a product unfit for its intended purpose.

In Kansas, product liability claims are governed by the Kansas Products Liability Act ("KPLA"), K.S.A. § 60-3301 *et seq.* The purpose of the KPLA is "to consolidate all product liability actions, regardless of theory, into one theory of legal liability." *Samarah v. Danek Med., Inc.*, 70 F. Supp. 2d 1196, 1202 (D. Kan. 1999) (quoting *Patton v. Hutchinson Wil-Rich Mfg. Co.*, 861 P.2d 1299, 1311 (1993)). Under K.S.A. § 60-3302(c), "all legal theories of recovery, e.g., negligence, strict liability, and failure to warn, are to be merged into one legal theory called a 'product liability claim.'" *Id.* (citing *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 931 (1990)) ("KPLA's provisions 'apply to actions based on strict liability in tort as well as negligence, breach of express or implied warranty, and breach of or failure to discharge a duty to warn or instruct.'").

Here, Plaintiff's various theories of recovery (negligence, strict liability and breach of warranty) merge into one legal theory called a product liability claim. Kansas law, however, recognizes three ways in which a product may be defective: (1) a manufacturing defect (a flaw in the manufacturing of the product); (2) a warning defect (a failure to adequately warn of a risk or hazard related to the product design; and (3) a design defect (a product which although perfectly manufactured contains a defect that makes it unsafe). *Baughn v. Eli Lilly & Co.*, 356 F. Supp. 2d

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Court, the "rule is based upon the theory that the physician acts as a learned intermediary between the drug manufacturer and the patient." *Humes v. Clinton*, 792 P.2d 1032, 1039 (Kan. 1990). The learned intermediary doctrine allows the manufacturer to "assume a patient places reliance on the physician's judgment and relieves the manufacturer of a duty to assist the physician in communicating with patients." *Id.* at 1040.

1177, 1183 (D. Kan. 2005). Plaintiff may, therefore, assert both design defect and failure to warn claims against Defendant. *See id.* at 1183 (“plaintiff may allege multiple defects in a single product”); *see also Wooderson v. Ortho Pharm. Corp.*, 681 P.2d 1038, 1051-54 (Kan. 1984) (discussing design defect and adequacy of the warning claims as they apply to manufacturer’s liability for allegedly distributing an unreasonably dangerous prescription drug); *see also Savina v. Sterling Drug*, 795 P.2d 915, 923 (Kan. 1990) (same); *Johnson v. American Cyanamid*, 718 P.2d 1318 (Kan. 1986) (plaintiff, who contracted polio after his daughter received her polio vaccine, brought action in state court for design defect and failure to warn).

Additionally, Kansas courts have recognized breach of warranty and negligence claims in products liability cases. *See Vanderwerf v. Smithklinebeechem Corp.*, 414 F. Supp. 2d 1023, 1026 (D. Kan. 2006) (analyzing breach of warranty claim, under Kansas law, in products liability prescription drug case); *see also Lindquist v. Ayerst Laboratories, Inc.*, 607 P.2d 1339, 1350 (Kan. 1980) (describing manufacturer’s duty to test under negligence principles). The Court will thus determine whether summary judgment in favor of Defendant is appropriate on Plaintiff’s design defect, breach of warranty, and negligence claims.

1. Strict Liability-Design Defect

In Count II of her Petition, Plaintiff asserts that “fenfluramine and dexfenfluramine” are defective because they cause valvular heart disease. Defendant responds that Plaintiff’s claim is not actionable on the ground of design defect because the drugs at issue are “unavoidably unsafe products” under Comment k of the Restatement (Second) of Torts §402A.

Under Kansas law, whether a design defect in a product exists is determined using the consumer expectation test. A plaintiff must show that the product is both in a defective condition

and dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics. *Delany v. Deere & Co.*, 999 P.2d 930, 945 (2000). The Supreme Court of Kansas has adopted the strict liability doctrine as set forth in Restatement (Second) of Torts § 402A. That section provides:

§ 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer  
(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if  
(a) the seller is engaged in the business of selling such a product, and  
(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it was sold.  
(2) The rule stated in Subsection (1) applies although  
(a) the seller has exercised all possible care in the preparation and sale of his product, and  
(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Comment k of section 402A provides an exception to the strict liability rule when the product can be characterized as “unavoidably unsafe,” and notes that these products are “especially common in the field of prescription drugs.” Comment k further states:

Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.

Comment k “is meant to shield a manufacturer from liability when the product cannot be designed more safely, not when the product was mismanufactured or was not accompanied by adequate warnings.” *Savina*, 795 P.2d at 924. The Supreme Court of Kansas has instructed that the exception to strict liability under Comment k must be applied on a case-by-case basis. *Id.*

To determine whether Comment k applies, the first question is whether the manufacturer provided adequate warnings of the risk of harm from use of its product, an issue which must be resolved by the trier of fact. *Wooderson*, 681 P.2d at 1057. The audience to whom these warnings must be directed is the medical community, not the consuming public. *Id.* at 1052. (citations omitted). Here, the parties concede that the evidence in this case creates a genuine issue of material fact concerning the adequacy of Defendant's warnings. That is, whether Defendant knew or should have known that the drugs at issue had a dangerous propensity to cause the kind of harm allegedly suffered by Plaintiff and whether Defendant failed to adequately warn Plaintiff's prescribing physician of such risk.<sup>8</sup>

Once the jury makes a determination on the adequacy of the warning issue, the Court must determine whether the exception to a design defect claim under Comment k applies. *See Savina*, 795 P. 2d at 925 (the trial judge should hear evidence on Comment k's application outside the presence of the jury and make a determination thereon). If the jury finds that the warning at issue was absent or inadequate, Defendant is not entitled to Comment k immunity. *See Menne v.*

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<sup>8</sup> The *Wooderson* court cited with approval *Ortho Pharmaceutical v. Chapman*, 388 N.E.2d 541 (Ind. Ct. App. 1979). *Id.* at 1051. In that case, the Court of Appeals of Indiana, Fourth District, held that "the duty to warn under Comment k does not arise until the manufacturer knows or should have known of the risk." The court concluded

"a product which is faultlessly designed and manufactured may be nevertheless unreasonably dangerous within the meaning of § 402A if not accompanied by proper warning.... A manufacturer can only be required to warn of risks known during the time in which the plaintiff was using the product in question, however he is charged with the knowledge of an expert in that field. In the case of ethical drugs, the manufacturer's duty is discharged if adequate warning is given to doctors, who act as learned intermediaries between the manufacturer and the ultimate user. To be adequate, a warning must be reasonable under the circumstances. As a practical matter, this is determined by application of negligence theory.

*Id.* at 1052.



*Celotex Corp.*, 861 F.2d 1453, 1457 n.3 (10th Cir. 1988) (referring to § 402A and Comment k and stating “failure to adequately warn of [reasonably foreseeable] hazards renders the product unreasonably dangerous”); *see also Deines v Vermeer Mfg. Co.*, 755 F. Supp. 350, 353 (D. Kan. 1990) (“A product may be perfectly manufactured and meet every requirement for its designed utility and still be rendered unreasonably dangerous through failure to warn of its dangerous characteristics.”).

Alternatively, if the jury finds that the warning was adequate, the Court must consider certain factors to determine whether the drugs at issue are unavoidably unsafe and, therefore, whether Comment k’s exception applies. The *Savina* court, quoting *Kearl v Lederle Laboratories*, 218 Cal. Rptr. 453 (1985), adopted the following approach in determining whether a given drug is unavoidably unsafe:

A trial court should take evidence as to: (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then existing risk posed by the product both was “substantial” and “unavoidable”; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review. In determining the first aspect of the second factor (i.e., whether the risk posed was “substantial”) a court should consider whether, at the time of distribution, the risk posed permanent or long-term disability (e.g., loss of body functions, organs or death) as opposed to mere temporary or insignificant inconvenience (e.g., skin rash, minor allergic reaction, etc.). In determining the second aspect of the second factor (i.e., whether the risk posed was “unavoidable”) a court should consider (i) whether the product was designed to minimize— to the extent scientifically knowable at the time it was distributed—the risk inherent in the product, and (ii) the availability— again, at the time of distribution— of any alternative product that would have as effectively accomplished the full intended purpose of the subject product.

*Savina*, 795 P. 2d at 925. If these questions are answered in the affirmative, Defendant’s liability will be tested by the standard of Comment k; otherwise, strict liability is the applicable test.

It should be noted that even if this Court were to conclude that the drugs at issue are “unavoidably unsafe,” Plaintiff can still pursue her design defect claim under a negligence theory.<sup>9</sup>

Syllabus paragraph 1 to *Johnson*, 718 P.2d 1318, states:

Although in standard products liability litigation plaintiff may utilize a strict liability design defect theory, such strict liability cause of action must be prohibited for public policy reasons where the product complained of is an unavoidably unsafe product within the purview of comment k to § 402A of Restatement (Second) of Torts (1963). In such special circumstances, plaintiff may proceed on a design defect theory only on the basis of negligence.

*See also Graham v. Wyeth Laboratories*, 666 F. Supp. 1483, 1498 (D. Kan. 1987) (“The cases which have addressed the issue are in agreement that even though a product is deemed “unavoidably unsafe,” the plaintiff may proceed under a negligence cause of action.”).

Because Defendant has failed to show that there is no genuine issue of material fact on Plaintiff’s design defect claim the Court will deny the motion for summary judgment on this issue.

## 2. Breach of Warranty

Count I of Plaintiff’s Petition charges that Defendant expressly and impliedly warranted that fenfluramine and dexfenfluramine were safe for their intended use, were free from manufacturing or production defects and would perform as indicated. Plaintiff further alleges that Defendant breached these warranties by “selling to Plaintiffs fenfluramine and dexfenfluramine that were not of merchantable quality, were unsafe and whose potential side effects were substantially untested.” Defendant argues that since Plaintiff admits that she did not rely on any

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<sup>9</sup> The Court disagrees with Defendant’s contention that Plaintiff’s negligence claims are premised only on failure to warn. Count II of Plaintiff’s petition also states a claim for negligent design defect: “Defendants owed a duty to Plaintiff ... to warn of any dangerous defects or side effects.” Plaintiff further alleges that “Defendants should have know [sic] that fenfluramine and dexfenfluramine caused unreasonably dangerous risks and serious side effects of which the general public would not be aware.” *See* Pl.’s Pet. at ¶ 86, 88.

representations made by Wyeth, it cannot be liable to Plaintiff for breach of express or implied warranties.

Under Kansas law, any affirmation of fact or promise made by the seller to the buyer or any description of the goods, which is made part of the basis of the bargain, creates an express warranty that the goods shall conform to the affirmation, promise or description. Kan. Stat. Ann. § 84-2-313 (2006). In an express warranty case, “a buyer must show only that the goods do not conform to the representation.” K.S.A. § 84-2-313 Kansas cmt. 5 (1996). The Official UCC Comment to 84-2-313 elaborates on what is necessary for an express warranty to be a part of the basis of the bargain and makes clear that it is not necessary to establish reliance to prevail on a breach of express warranty claim:

No particular reliance on such statement [factual statements describing such goods] need be shown in order to weave them into the fabric of the agreement [as an express warranty].... The issue is normally one of fact.... The basic question remains the same: what statements of the seller have in the circumstances and in objective judgment become part of the basis of the bargain?

The 1996 Kansas Comment to K.S.A. 84-2-313 further states:

Under this section, a representation by the seller must become ‘part of the basis of the bargain’ before it creates an express warranty. This requirement is the Article 2 counterpart to the pre-Code requirement of reliance, but is much less stringent. The buyer need not show any specific or particular reliance. See *Young & Cooper, Inc. v. Vestring*, 214 K. 311, 521 P.2d 281 (1974)....

*See also Olathe Mfg. v. Browning Mfg.*, 915 P.2d 86, 94 (Kan. 1996) (quoting to Kansas Comment 1983 to this section). The Court concludes that Kansas law does not require Plaintiff to show that she relied on Wyeth’s statements to submit her breach of express warranty claim to a

jury.<sup>10</sup> The Court will, therefore, deny Defendant's motion for summary judgment on this claim.

"To demonstrate a breach of the implied warranty of merchantability, plaintiff must show that the goods were defective, that the defect was present when the goods left the manufacturer's control, and that the defect caused the injury sustained by plaintiff." *Vanderwerf*, 414 F. Supp. 2d at 1026 (quoting *Dieker v. Case Corp.*, 7 P.3d 133, 147 (2003)); K.S.A. § 84-2-314. The Court has determined that Defendant has failed to establish that summary judgment is appropriate on Plaintiff's strict liability- design defect claim. Likewise, the Court will deny summary judgment on Plaintiff's implied warranty of merchantability claim. *See Vanderwerf*, 414 F. Supp. 2d at 1026 ("A pleading that is adequate for a strict liability claim will suffice for an implied warranty of merchantability claim.").

Accordingly, the Court will deny Defendant's motion for summary judgment on Plaintiff's breach of express and implied warranty claims.

### 3. Negligent Failure to Test

As noted earlier, the Court disagrees with Defendant that Plaintiff's negligence claim only alleges a failure to warn. Count IV of Plaintiff's petition also alleges Defendant negligently failed to test the drugs at issue.<sup>11</sup> In *Lindquist*, 607 P.2d at 1350 (quoting 1 Hursh and Bailey,

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<sup>10</sup> Defendant cites to *Comeau v. Rupp*, 810 F. Supp. 1127, 1161 (D. Kan. 1992), for the proposition that, under Kansas law, reliance is a necessary element in an action for breach of warranty. The court in *Comeau* cited to *Land v. Roper Corp.*, 531 F.2d 445, 448 (10th Cir. 1976) in support of its claim that Kansas requires reliance for breach of warranty claims. In *Land*, the court's decision was based on an analogy to U.C.C. § 2-313 which required reliance at that time, but no longer does, *see Roper*, 531 F.2d at 448.

<sup>11</sup> In addition to her negligent failure to warn and negligent design defect claims, Plaintiff's petition states, "Defendants breached their duty of reasonable care to Plaintiffs in that Defendants failed to [c]onduct sufficient testing, which, if properly performed, would have shown that fenfluramine and dexfenfluramine had serious side effects, including primary pulmonary

American Law of Products Liability 2d § 2:29, p. 214 (1974)), the Supreme Court of Kansas recognized that a manufacturer has a duty to test and inspect its products:

The rule is that a manufacturer has a duty to make such tests and inspections, during and after the process of manufacture, as should be recognized as being reasonably necessary to secure the production of a safe product; and a manufacturer who negligently fails to use reasonable care in making such tests and inspections, and thereby produces a defective article which causes damage while being put to an ordinary, anticipated use, is liable for such dangers. The plaintiff cannot succeed where he fails to allege or prove that tests or inspections would have been effective.

Federal courts interpreting Kansas law note that the plaintiff must prove that the manufacturer's failure to test its product resulted in a defected product that caused injury to plaintiff. *Burton v. R.J. Reynolds Tobacco Co.*, 397 F.3d 906, 920 (10th Cir. 2005). In *Richter v. Limax Int'l*, 45 F.3d 1464, 1467 (10th Cir. 1995), the Tenth Circuit Court of Appeals affirmed the district court's ruling that "Wooderson did 'not require that a manufacturer warn users of its products of dangers which, although not known by anyone in the field, could be found by reasonable testing.'" *Id.* The court explained that while Kansas law recognizes a manufacturer's duty to test, that duty is limited to testing only for specific design and manufacturing defects. *Id.*<sup>12</sup> The court concluded that "manufacturers do not have a duty to test for inconceivable dangers, nor do they have a duty to test for every conceivable danger. They do have a duty to warn of dangers of harmful effects arising from foreseeable use and misuse of a product that are known or are

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hypertension and heart valve disorders." Pl.'s Pet. at ¶ 87.

<sup>12</sup> The district court reasoned that "policy considerations might dictate this result to avoid placing the onerous burden on manufacturers to conduct 'all possible tests for dangers which may result from all possible foreseeable uses, even if those uses or those dangers have yet to occur anywhere in the world.'" *Richter*, 45 F.3d at 1468 (quoting *Richter v. Limax Int'l Inc.*, 822 F. Supp. 1519, 1524 (D. Kan. 1993)).

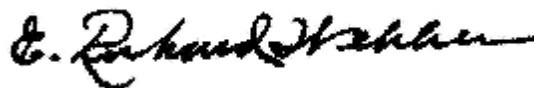
readily foreseeable in the state of art.” *Id.* at 1467.

Here, Defendant has failed to provide any evidence to show that Plaintiff cannot prevail on her negligent failure to test claim. Because the Court has concluded that there is a genuine issue of material fact that the drug at issue was defectively designed, Plaintiff will be permitted to submit her negligent failure to test claim to the jury. The Court reiterates that Plaintiff must provide evidence to show what tests should have been performed and how any such testing would have prevented her injuries. *Messer v. Amway Corp.*, 106 Fed. Appx. 678, 685 (10th Cir. 2004). Accordingly, Defendant’s motion for summary judgment on Plaintiff’s negligence claim will be denied.

Accordingly,

**IT IS HEREBY ORDERED** that Defendant American Home Products Corporation’s Motion for Partial Summary Judgment [doc. #38] is **DENIED**. The Final Pretrial Conference is set for **May 25, 2007** at **9:00 a.m.** This matter remains set on a three week docket beginning **June 4, 2007** at **8:30 a.m.**

Dated this 7th day of May 2007.



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E. RICHARD WEBBER  
UNITED STATES DISTRICT JUDGE